

REMARKS

This Amendment is submitted in reply to the non-final Office Action mailed on May 5, 2010. A Petition for a three month extension of time is submitted herewith this Amendment. The Director is authorized to charge \$1,110.00 for the Petition for a three month extension of time and any additional fees that may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 3712036-00753 on the account statement.

Claims 1-21 are pending in this application. Claims 9-11 and 15-19 were previously withdrawn. In the Office Action, Claim 14 is rejected under 35 U.S.C. §112. Claims 1-8, 12-14, 20 and 21 are rejected under 35 U.S.C. §103. In response, Claim 14 has been amended. The amendments do not add new matter and are supported in the specification at, for example, page 8, line 28-pge 9, line 4. In view of the amendments and/or for the reasons set forth below, Applicants respectfully submit that the rejections should be withdrawn.

In the Office Action, Claim 14 is rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Specifically, the Patent Office asserts that “[i]t is not clear how a tablet form could be selected from a capsule, a solution, a suspension, or a syrup.” In response, Claim 14 has been amended to delete the word “tablet.” Based on at least these reasons, Applicants believe that Claim 14 now fully complies with the requirements of 35 U.S.C. §112, second paragraph.

Accordingly, Applicants respectfully request that the rejection of Claim 14 under 35 U.S.C. §112, second paragraph, be reconsidered and withdrawn.

In the Office Action, Claims 1-8, 12-14 and 20-21 are rejected under 35 U.S.C. §103(a) as being obvious over JP 09107880 to Osanai (“*Osanai*”), in view of Journal of Agricultural and Food Chemistry to Edenharder et al. (“*Edenharder*”), Eur J. Nutr to Faulks et al. (“*Faulks*”) and Royal Society of Chemistry to Hovari et al. (“*Hovari*”) and further in view of JP 2003164261 to Imazawa et al. (“*Imazawa*”). Applicants respectfully traverse the rejection for at least the reasons set forth below.

Independent Claims 1, 12 and 14 recite, in part, a primary composition at least essential lipophilic and hydrophilic bioactive components of a material selected from the group consisting of whole fruit, vegetable and plant material, excluding insoluble fibers, wherein the essential

lipophilic and hydrophilic bioactive components are extracted from the material by milling the material in the milk or milk protein-containing carrier and the insoluble fibers are removed by centrifuging the carrier after milling.

As taught by Applicants' specification, essential bioactive components extracted from fruits or plant materials are well-known and widely used in the food industry. However, conventional techniques for extracting such bioactive components only extract some of the bioactive components from the fruit or plant material. For example, water extraction techniques, in which the bioactive components are extracted from insoluble fibers, preserve the natural image and nutritional functions of the bioactive components but are not very efficient. Solvent extraction techniques, while more efficient than water extraction, still fail to extract a substantial portion of the bioactive components from the fruit or plant material and simultaneously impair the nutritional functions of the bioactive components. See, specification, page 1, line 23-page 2, line 28. Therefore, traditional water and solvent extraction techniques are only able to extract a few compounds of the fruit or plant material, leaving some other bioactive materials in the remaining material. For example, polysaccharides, polyphenols and other non-lipophilic compounds are not extracted together with the lipophilic components such as carotenoids, lipophilic vitamins and other lipids.

The essential bioactive components of the present claims are extracted from fruits or plant materials by milling the material in a milk or milk protein-containing carrier. Milling the material contained in the milk or milk protein-containing carrier allows for the formation of much smaller particles of ground plant material, allowing more efficient access by the milk or milk protein-containing carrier to both the water-soluble and oil-soluble bioactives of the plant material. Furthermore, centrifuging the milk or milk protein-containing carrier after milling of the fruit or plant materials removes the insoluble fibers and allows the essential lipophilic and hydrophilic bioactive components to have improved bioavailability and miscibility in the milk or milk protein-containing carrier. See, specification, page 4, lines 1-3.

The present compositions, thus, are produced by processes that allow for the extraction of a greater amount of bioactive materials than with traditional water or solvent extraction techniques. The fruit or plant material is mixed in a milk or milk protein-containing medium and separated from insoluble fibers to obtain an aqueous suspension. By using a milk or milk protein-containing carrier to extract the bioactive components from the fruit or plant material and

centrifuging the milk or milk protein-containing carrier, the present claims provide bioactive components with improved miscibility, stability and bioavailability over conventional extraction techniques without the use of organic solvent residues. See, specification, page 3, lines 19-page 4, line 10; page 7, lines 5-12. By using milk or milk proteins, soy-milk or milk-like proteins from plants, the primary composition of the present invention provides a similar profile of the important nutrients like the whole fruit. Furthermore, by also removing the insoluble fibers through centrifugation, the primary composition of the present claims can be efficiently produced. See, specification, page 4, lines 1-3. In contrast, Applicants respectfully submit that the skilled artisan would have no reason to combine the cited references to arrive at the present claims because the cited references are directed to unrelated products that have completely different objectives.

Osanai is entirely directed to cow's milk containing vegetables whose main constituent is rapa gourd, wherein the vegetable containing rapa gourd is mixed with cowsmilk. See, *Osanai*, pages 5-6. *Edenharder* is entirely directed to the isolation and characterization of antimutagenic flavonoids from spinach. See, *Edenharder*, Abstract. Indeed, the entire disclosure of *Edenharder* is directed to the purification of antimutagens from spinach by preparative and micropreparative HPLC from a methanol/water extract of dry spinach after removal of lipophilic compounds. See, *Id.* As such, not only is the subject matter of *Edenharder* nonanalogous art when compared to *Osanai* and the present claims, but *Edenharder* teaches away from the present claims when *Edenharder* discloses removal of lipophilic compounds from the spinach extract.

Similar to *Edenharder*, *Faulks* is entirely directed to the quantification of β -carotene and lutein absorption from a representative green vegetable with different degrees of processing, using both mass balance and metabolic modeling of triglyceride-rich lipoprotein plasma fraction. See, *Faulks*, Summary. Like *Edenharder*, the green vegetable of *Faulks* is spinach and the entire disclosure is directed to the kinetics of gastro-intestinal transit and carotenoid absorption and disposal in ileostomy volunteers fed spinach meals. See, *Faulks*, Summary and Introduction. As such, *Faulks* is also nonanalogous art when compared to *Osanai* and the present claims.

Hovari is entirely directed to the effects of flavanoids on human health and the content of flavonoids in specific vegetables. See, *Hovari*, Introduction, Table 1. *Imazawa* is entirely directed to extraction efficiency and preparation of juice in a short time for industrialization. See, *Imazawa*, paragraphs 18 and 19. *Imazawa* is entirely directed to processes that include

pulverizing the coffee beans, fruits, vegetables, etc., adding a dispersing media to the pulverized coffee beans, fruits, vegetables, etc., and then homogenizing the mixture. See, *Imazawa*, Working Examples.

As such, the cited references are clearly directed to unrelated products or processes that have completely different objectives. Moreover, none of the cited references even recognizes the benefits obtained from the presently claimed compositions including, for example, improved bioavailability and miscibility from extracted fruits or plant materials by milling the material in a milk or milk protein-containing carrier and centrifuging the milk or milk protein-containing carrier after milling of the fruit or plant materials to remove the insoluble fibers. Such treatments allow the essential lipophilic and hydrophilic bioactive components to have improved bioavailability and miscibility in the milk or milk protein-containing carrier. See, specification, page 4, lines 1-3.

Further, if the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there exists no reason for the skilled artisan to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). In fact, Applicants submit that what the Patent Office has done here is to apply hindsight reasoning by attempting to selectively piece together teachings of each of the references in an attempt to recreate what the claimed invention discloses. Indeed, the skilled artisan must have a reason to combine the cited references to arrive at the present claims. Applicants respectfully submit that such a reason is not present in the instant case.

For at least the reasons discussed above, Applicants respectfully submit that Claims 1-8, 12-14, 20 and 21 are novel, nonobvious and distinguishable from the cited references.

Accordingly, Accordingly, Applicants respectfully request that the rejections of Claims 1-8, 12-14, 20 and 21 under 35 U.S.C. §103(a) be reconsidered and withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly request an early allowance of the same. In the event there remains any impediment to allowance of the claims which could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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